Aim of Study

The aim of this study was to compare the effect of pulpotec and calcium hydroxide intracoronal dressing on interappointement pain relief for symptomatic posterior teeth with acute pulpitis with apical periodontitis utilizing:

1- Visual Analogue scale **(VAS)** at different time intervals;

a- Preoperative.

b- After 8, 12, 24, 48 hours postoperatively.

c- After 1, 3, 6 months.

2- Clinical and radiographic follow up for 1, 3, 6 months.

Materials & Methods

A-Materials & devices used in this study:

Table (1):Materials used in this study.

Material/ Device	Description
Calcium Hydroxide	Dycal, Dentsply,USA
Pulpotec	PD Vevey Switzerland It`s presentation of: Powder: Polyoxymethylene, Iodoform, excipient. Liquid: Dexamethasone Acetate, Formaldehyde, Phenol, Guaiacol, excipient.
Thermal vitality tester	Ethyl choride Spray, Walter Ritter GmbH.co,Germany.
Electric vitality tester	Desensitron 2, electronic sdivision,USA.
A periapical film	Kodak intraoral Periapical films, KODAK, USA.
Anaesthesia	Mepivacaine-L Carpule, Alexandria Company for Pharmaceuticals and Chemical Industries, Egypt.
Sodium hypochlorite	Clorox, Egyptian Co. For household products under license of color x Co., Egypt.
Amalgam filling	Ventura ng cap, Madespa, Espana(Spain).
Zinc Phosphate cement	Acrostone, EL-Salam City Cairo, Egypt.
X-ray machine	Planmeca Intra X-ray Unit, Planmeca, Finland.

B-Trial design:

The trial design of this study is parallel randomized controlled design.Randomized controlled trial (RCT) which is one of the simplest, most powerful and revolutionary tools of research. [13] (Fig 2).

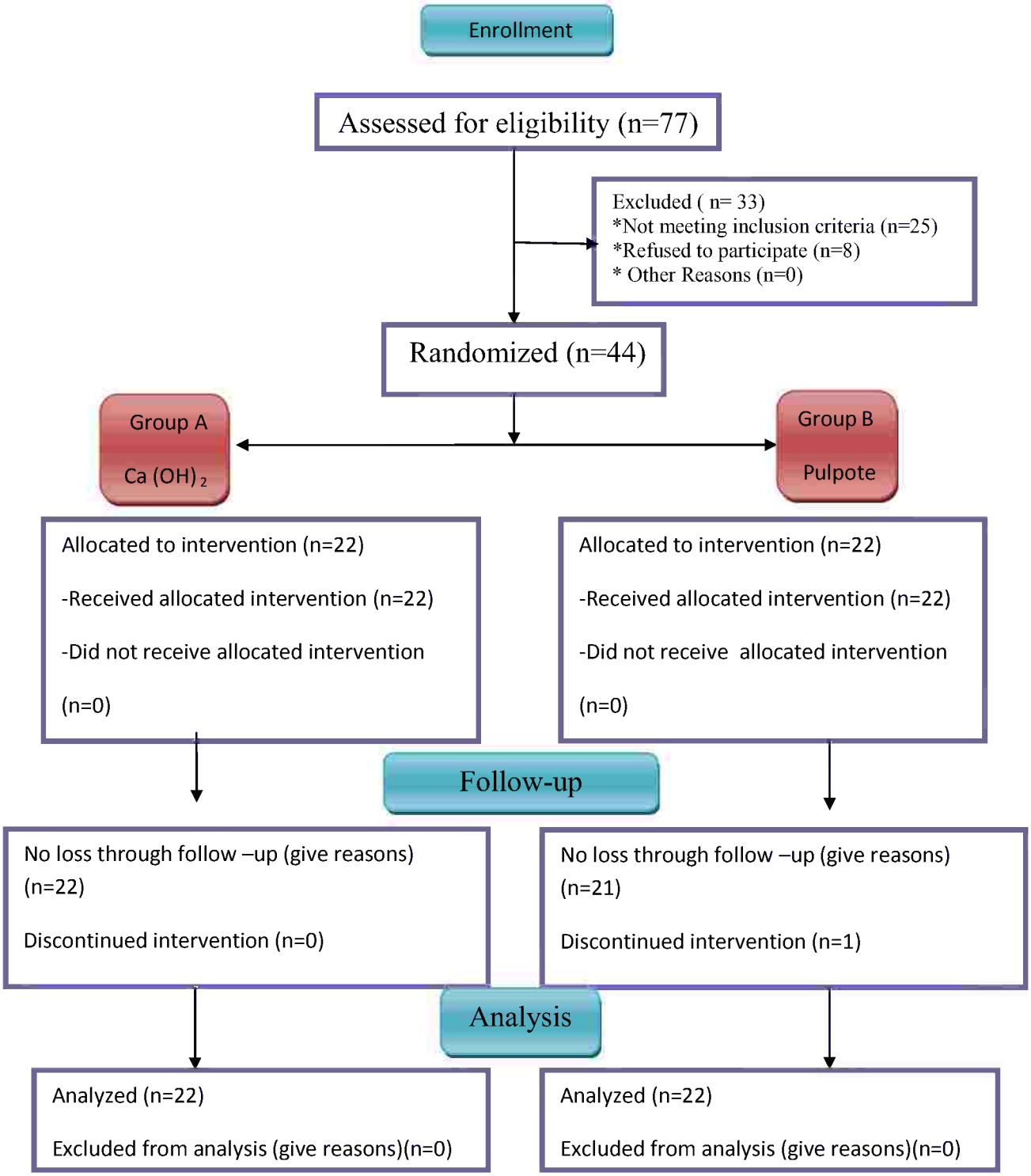


Figure 2:CONSORT 2010 flow diagram of the trial.

C- participants:

Eight students in this research works on 44 similar cases for each one following the same materials and methods and the aim of the study. All of 44 subjects were selected from the out-patient clinic at the Endodontic Department at Cairo University according to the following:

1-Inclusion Criteria:

All patients were aged between 15 and 55 years with no sex predilection.

Dental condition:

Carious Posterior teeth with acute pulpitis with apical periodontitis clinically and radiographically diagnosed with no bone loss, mobility or periapical destruction.

Medical condition:

- Not addicted to any drug that changes the pain threshold level or any chronic medication.
- Medically free with no history of allergy to any medication.
- Not taking any palliatives or analgesics before the treatment by 24 hours
- A cooperative patient.

2-Exclusion criteria

- Endocrine diseases contraindicating endodontic treatment or affecting the tissues regenerative power like Diabetes, Hypothyroidism and Hyperthyroidism.
- Systemic diseases like Anemia, Leukemia and Hemorrhagic disorders.
- Infectious diseases like Hepatitis, Tuberculosis and AIDS.
- Cardiovascular diseases like Coronary Artery Disease, Hypertension, and Myocardial infarction.
- Psychological disturbance.
- Allergy to the medications like pulpotec, $Ca(OH)_2$ or to the anasethia .
- Pregnancy or lactation.
- Uptake of analgesics or anti-inflammatory drugs within 24 hours of treatment.
- Bad oral hygiene.

3- Setting and location:

Patient selection was done from patients attending or referred for root canal treatment to the postgraduate clinics in the Department of Endodontics, Faculty of Oral and Dental Medicine, Cairo University, Egypt.

From 77 enrolled patients, 44 patients were included in the study. The trial design followed the CONSORT 2010 flow diagram [17] (Fig. 2). This controlled parallel- designed clinical trial was approved by the committee of ethics, Cairo University. The operator worked in the Department of Endodontics on Sirona dental units and used Planmeca X-ray machine. Operator was a master degrees student in the Department of Endodontics.

F-Sample Size:

Forty four participants in this research were assigned to group, 22 patients in each group, randomly divided into 2 equal groups:

1) GROUP A: will receive **Calcium Hydroxide** dressing (Fig. 3).

Figure 3: Calcium Hydroxide Materials.

2) GROUP B: will receive **Pulpotec** dressing (Fig. 4).

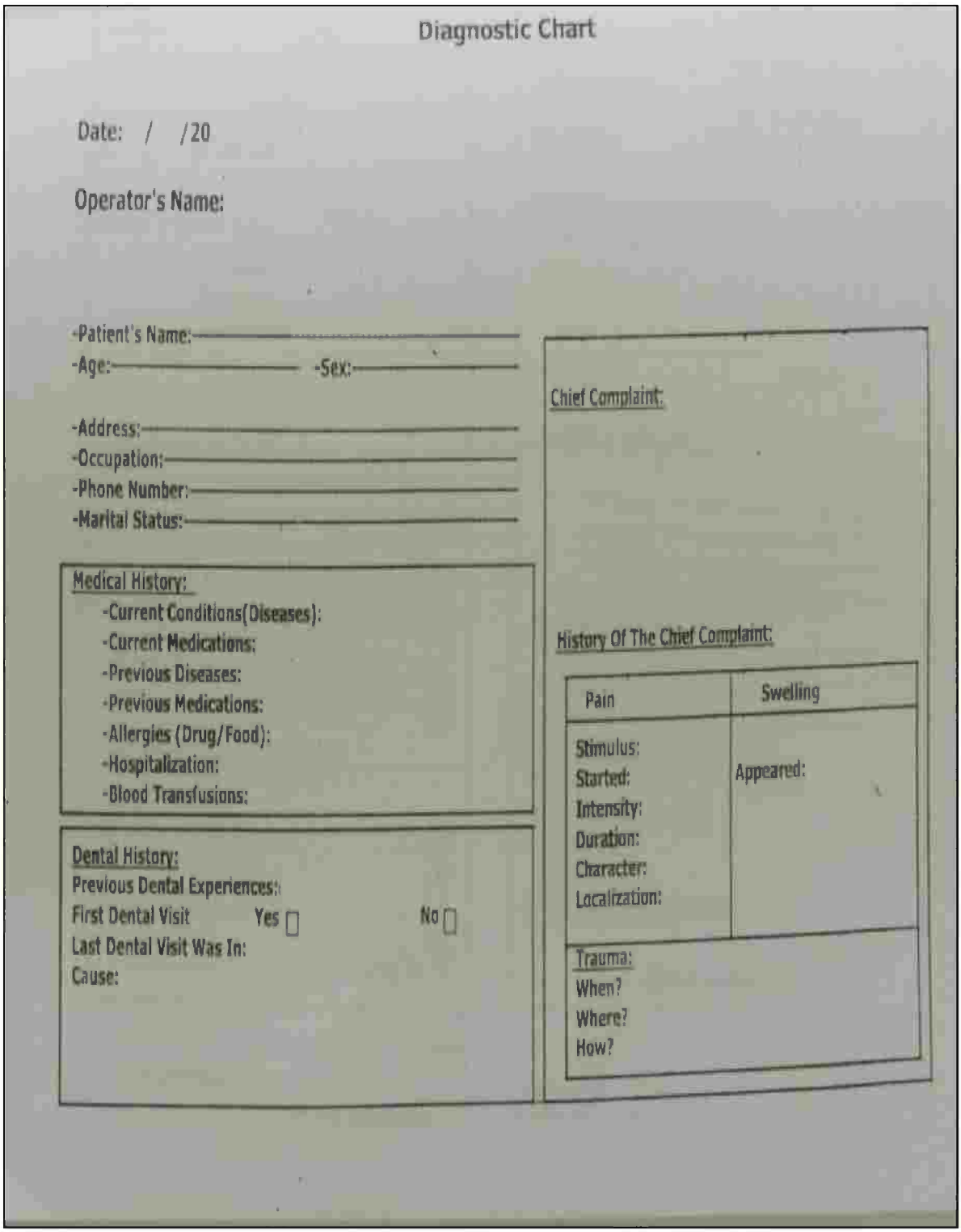
Figure 4: Pulpotec Materials**.**

D- Intervention:

After the explanation of the treatment procedures, the patient was asked to follow general instructions and to sign a printed consent (appendix I) that explained the aim of the study and obligated the patient to fill the pain diary before treatment, after 8 hours, 12 hours, 24 hours, 48 hours postoperatively, then after 1, 3, 6 month.

In the diagnosis of the acute pulpitis with apical periodontitis the following procedure was followed [109,110].

Dental and medical histories, clinical and radiographic data for each tooth were collected from all patients participating in this research in forms presented in (Fig. 5,6). These forms were copied from the text book 2012 of Department of Endodontics, Faculty of Oral and Dental Medicine, Cairo University, Egypt.



Diagnostic Chart

Date: / /20

Operator's Name:

-Patient's Name:
-Age: -Sex:

-Address:
-Occupation:
-Phone Number:
-Marital Status:

Medical History:
-Current Conditions(Diseases):
-Current Medications:
-Previous Diseases:
-Previous Medications:
-Allergies (Drug/Food):
-Hospitalization:
-Blood Transfusions:

Dental History:
Previous Dental Experiences:
First Dental Visit Yes ☐ No ☐
Last Dental Visit Was In:
Cause:

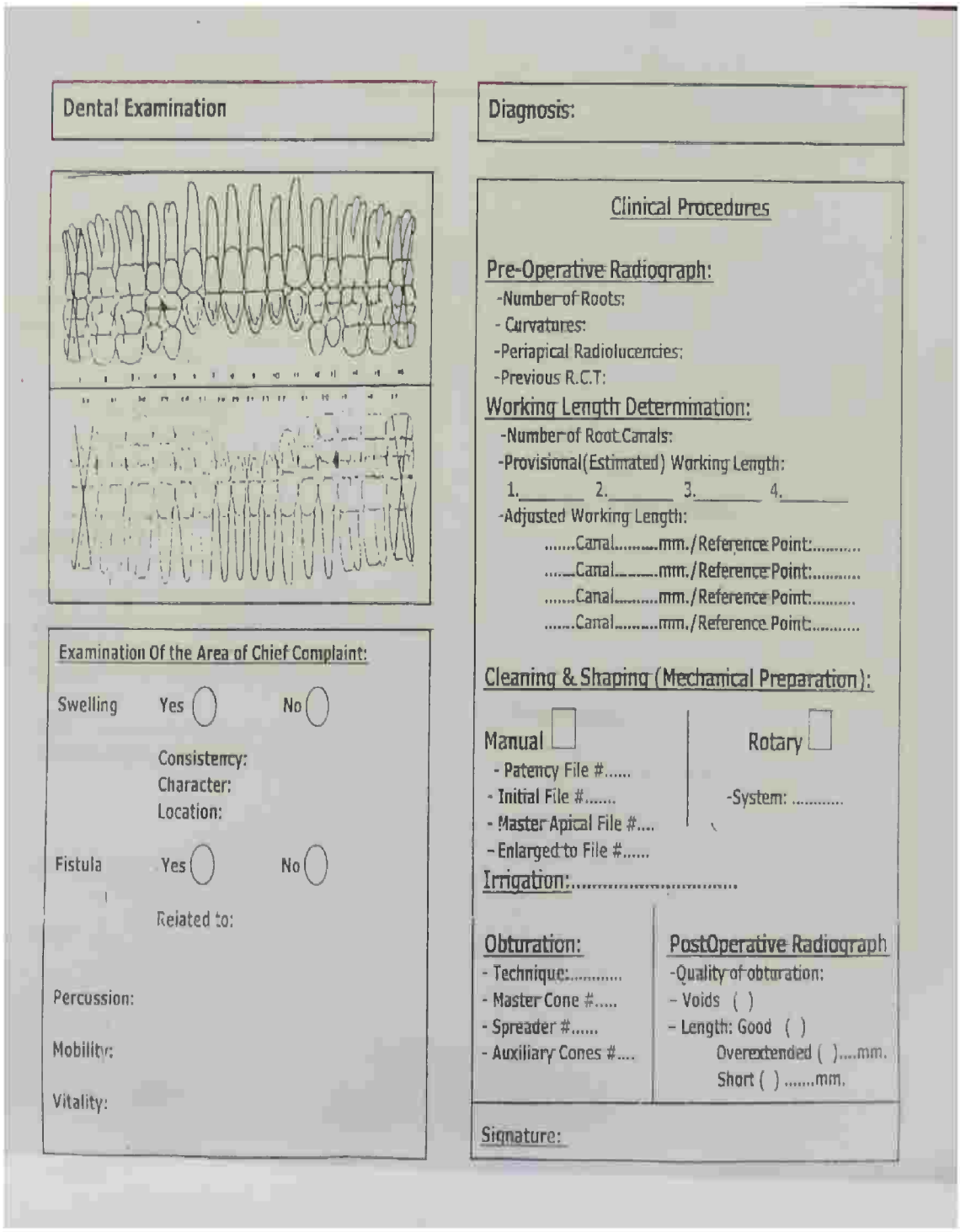
Chief Complaint:

History Of The Chief Complaint:

Pain	Swelling
Stimulus: Started: Intensity: Duration: Character: Localization:	Appeared:

Trauma:
When?
Where?
How?

Figure 5: Diagnostic Sheet (1)



Dental Examination

Examination Of the Area of Chief Complaint:

Swelling Yes ◯ No ◯

Consistency:
Character:
Location:

Fistula Yes ◯ No ◯

Related to:

Percussion:

Mobility:

Vitality:

Diagnosis:

Clinical Procedures

Pre-Operative Radiograph:

-Number of Roots:
- Curvatures:
-Periapical Radiolucencies:
-Previous R.C.T:

Working Length Determination:

-Number of Root Canals:
-Provisional(Estimated) Working Length:
1._____ 2._____ 3._____ 4._____
-Adjusted Working Length:
.....Canal.....mm./Reference Point:.....
.....Canal.....mm./Reference Point:.....
.....Canal.....mm./Reference Point:.....
.....Canal.....mm./Reference Point:.....

Cleaning & Shaping (Mechanical Preparation):

Manual ☐ Rotary ☐

- Patency File #.....
- Initial File #.....
- Master Apical File #....
- Enlarged to File #.....

-System: .....

Irrigation:.....

Obturation:
- Technique:.....
- Master Cone #.....
- Spreader #.....
- Auxiliary Cones #....

PostOperative Radiograph
-Quality of obturation:
- Voids ( )
- Length: Good ( )
Overextended ( )....mm.
Short ( ) .....mm.

Signature:

Figure 6: Diagnostic Sheet (2)

Medical and dental history:

All the information about the patient's medical and dental history had been obtained orally and written in the diagnostic sheet to evaluate the data and determine if any conditions or excluded criteria exist that will affect, alter or delay any necessary dental treatment.

Chief complaint:

The chief complaint should be recorded in the patient's own words.

Pain:

A complete history of the pain was recorded to determine the following characteristics:

- Character
- Duration
- Frequency
- Intensity
- Provoking & relieving factors
- Localization

Pain associated with acute pulpitis with apical periodontitis is characterized by:

1) Mild, moderate or severe: according to the pain threshold of the patient, sensitivity of the pulpal tissue to irritation and severity of the irritant itself.
2) Evoked by an irritant: hot,cold, chewing and/or suction.
3) Lingers for long time after removal of the cause.

4) May increase at night (lying down) or bending.
5) Not to be continued pain.

Patient who match the inclusion criteria such that they are not suffering from any exclusion criteria and complaining of acute pain related to a posterior tooth are then transferred to the dental chair for the clinical examination [109,110,111,112].

Clinical Examination:

A complete examination covers the following three areas: The general examination, the extra-oral head and neck soft Tissue examination, and the intra-oral examination.

General examination:

The general examination begins as soon as the patient enters the dental office. Observe the patient'sweight, length and any abnormalities like lesions or scars [111].

Observation of the color of the eyes and skin: any change in the color of the eyes or skin might be indication to any underlying systemic disease that is not recognized.

Extra-oral head and neck examination:

- Observe the head and neck by focusing on the area around the jaws and detect any significant asymmetry, such as previous surgeries, scars, tumors, and infections.
- Examine the head and neck lymph nodes to detect any abnormal swelling, lymphadenopathy or tenderness. Abnormal lymph nodes are generally larger, may be tender, and can be an indication of an inflammation or that drainage of infection has occurred. A non-tender enlargement may indicate cancer or lymphoma.
- Examine the TMJ for any abnormalities like swelling or clicking sound or any signs of inflammation [111].

Intra-oral examination:

- Visual Examination:

Using mirror and probe for examination of the oral soft tissue; tongue, cheek, soft and hard palate, and gingiva to detect any abnormalities in color, contour, pocket depth or texture.

Etiology of acute pulpitis with apical periodontitis should be one or more of the following:

1) Deep carious lesion approximating pulp (pulpal exposure confirmed clinically).
2) Large metallic restorations with no underlying insulating base.
3) Recurrent caries below a restoration.

- Palpation:

The labial and buccal vestibules surrounding the affected tooth were palpated. Tenderness in the area was considered as a sign of periodontitis which was considered inclusive. The presence of any swelling in the vestibule was considered excluding.

- Percussion:

Using the handle of the mirror the tooth was slightly tapped on the occlusal surface and the response of the patient was detected for any pain or tenderness which was considered as a sign of periodontitis.

- Mobility test:

To evaluate the integrity of the attachment apparatus surrounding the tooth by using handles of two instruments and moving it laterally and vertically in its socket.

- Vitality test:

  - Thermal vitality test by Ethyl chloridespray (Fig. 7).
  - Electric pulp tester (Fig. 8) was used to geta lower response compared to the control tooth.

Figure 7: Ethylchloride spray –cold pulp test.

Figure 8: Electric vitality test.

Radiographic examination:

Using an x-ray machine to take a periapical radiographic film for the affected tooth with the surrounding periodontium was performed by using the bisecting angle technique [109].

Radiographic evidence may reveal normal pulp, calcifications, narrow pulp chamber, "calcified" canals, an enlarged PDL or condensing osteitis[124]. Cases with condensing osteitis will be excluded.

E- Randomization:

Randomization is of central importance in clinical trials. It prevents selection bias and insures against accidental bias. It produces comparable groups, and eliminates the source of bias in treatment assignments. Finally, it permits the use of probability theory to express the likelihood of chance as a source for the difference between outcomes.

Randomization insures that each patient have an equal chance of receiving any of the treatments under study, generate comparable intervention groups which are alike in all important aspects except for the intervention each group receives. It also provides a basis for the statistical methods used in analyzing data [113,114].

1- Sequence generation:

The sequence generation was done for the patients numbers (from 1 to 44) using computer sequence generation. Which gave a table for group A and group B with randomized patients numbers (22 numbers in each group) (fig.9).

This is the sequence:

(A) $Ca(OH)_2$	(B) pulpotec
7	32
28	19
39	35
8	36
11	6
13	34
22	38
5	1
41	27
26	30
4	33
10	12
23	18
14	2
43	16
21	42
15	31
44	17
25	3
37	9
20	40
24	29

Note :(A) $Ca(OH)_2$, (B) Pulpotec

Figure 9: Random Sequence Numbers Generation.

2- Allocation concealment mechanism:

The whole trial should be double blinded or masked, meaning that neither the patient nor the dentists are aware of the treatment randomly assigned to the patient [115].

It is the procedure for protection the randomization process so that the treatment to be allocated is not known before the patient is entered into the study.

For the allocation concealment mechanism, 44 papers (each was folded for times) with a number from 1 to 44 were placed inside opaque envelops. The number in the envelope determined which material was to be used for that patient according the table generated by the computer. The partner prepared the material for the operator according to that number.

Without adequate allocation concealment, even random, unpredictable assignment sequences can undermine our goal. Knowledge of the next assignment could lead to the exclusion of certain patients based on their prognosis because they would have been allocated to the perceived inappropriate group. Moreover, knowledge of the next assignment could lead to direct some participants to perceived proper groups, which can easily be accomplished by delaying a participant's entry into the trial until the next appropriate allocation appears.

Avoidance of such bias depends on the prevention of fore knowledge of treatment assignment. Allocation concealment shields those who admit participants to atrial from knowing the upcoming assignments. The decision to accept or reject a participant should be made, and informed consent should be obtained, in ignorance of the upcoming assignment [116].

3- Implementation:

The random allocation sequence was done in the center of evidence based Dentistry – Cairo University. However, allocation concealment and participant assignment to the intervention were done by the partner.

F- Blinding:

Blinding means procedures that prevent study participant, operator, or outcome assessor (who evaluated the collected data) from knowing which intervention was received. A double blind study is a scientific experiment where involved individuals are denied certain information that may cause conscious or subconscious bias on their part, nullifying the results.

This research was double blind study (patient, operator) only assessor knows the type of the material used for dressing neither the patient nor theoperator.

Blind assessments produced significantly lower and more consistent scores than open assessments [117].

The procedures:

- Treatment of all selected cases was completed in a single visit using vital pulpotomy.
- Operative procedures were completed as follow vital pulpotomy operation [33, 118].

1. Patient was anesthetized using a non-aspirating syringe with 1.8 ml Mepivacaine HCL 2% -Levonordefrin 1:20000. Infiltration was used

for the maxillary teeth and inferior alveolar nerve block was used for the mandibular teeth. The effect of the anesthesia was confirmed by probing the gingiva adjacent to the tooth before proceeding.

2. All caries were removed and the cavity outline was established.The observation of perfuse bleeding from exposure sites indicates vital coronal pulp tissue.
3. The entire roof of the pulp chamber was removed using a high-speed non-end cutting bur with copious waterspray.
4. All the coronal pulp was amputated using a slow-speed #6 or#8 round bur with coolant or spoon excavator.
5. Teeth were isolated by rubber dam.
6. The cavity was irrigated with sodium hypochlorite 5 %[119,120] and was lightly dried with cotton pellets.
7. Hemorrhage was controlled with a cotton pellet applied with Pressure.
8. In case of pulpotec dressing a glass slab and spatula was used to obtain a ball of thick putty paste consistency mixed according to the manufacturer instruction and creamy paste In case of calcium hydroxide dressing.
9. Shaped the ball of pulpotec into a cylinder and inserted directly into the pulp-chamber using ball burnisher and placed against the pulp orifices.
10. Calcium hydroxide carried to the cavity using plastic instrument and adjusted to the orifices of the canals.
11. After application of the dressing, zinc phosphate cement was used as a base [121,122] then the cavity sealed by amalgam filling for maximal seal ability for long term protection of the dressing [118.123].
12. Occlusion was checked & relived if needed to avoid further irritation and trauma for the periodontium delaying its healing.

G- Outcome:

1.Primary outcome

Is the degree of pain after the procedure which will be measured by the Visual Analogue Scale (VAS) (Figure 10A).

VAS is often used in epidemiologic and clinical researches to measure the intensity and frequency of various symptoms particularly pain. It is generally estimated by patients themselves but sometimes used to get help opinions from health professionals.

VAS are more sensitive to small changes than are simple descriptive ordinary scales in which symptoms are rated, for example,as mild or slight, moderate, or severe to agonizing [(124)].

The VAS scale was presented in different ways to facilitate the patient understanding and recording, of the pain intensity. It expressed pain numerically and verbally. Numerical description was presented as a scale begins from zero (0) to ten (10), from which the patient choose a number according to the pain intensity. However, verbal description was represented as no pain, mild and severs pain which corresponded to (0), (5), and (10) respectively.

2.Secondary outcome

For both groups, accurate examination is mandatory both clinically and radiographically [(111,1112,125,126)] in each follow up visits during 1month, 3months, and 6 months using VAS (Figure 10 B) to determine the intervention results (signs of success or failure) (Table 2) as following :

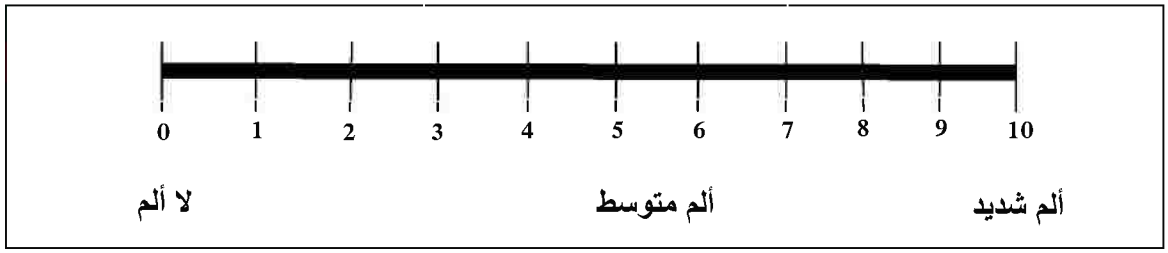
- **Clinical success**: signs & symptoms (S&S) should improve or disappear post-operatively.
- **Clinical failure**: persistent S&S post-operatively OR become worsened.

Item	SUCCESS	FAILURE
1)clinical evaluation	-Pain →disappeared or decreased by time. -No development of swelling or sinus tracts. -No mobility or periodontal defect. - no furcation involvement - No sensitivity to percussion. -Normal +ve vitality tests.	-Increasing or persistence of pain. -Development of swelling or sinus tracts. -Increasing mobility of treated tooth beyond the physiologic limits. -Furcation involvement -Loss of tooth function.
2)Radiographic evaluation	-Normal lamina Dura& periodontal membrane space. -Reduction or elimination of previous periapical bony rarefaction by time. -Neither internal nor external root resorption.	-Increasing or Persistence or widening of lamina Dura by time. -Increasing or Persistence of periapical bony rarefaction by time. -Development of peri-apical radiolucencies. -Development of internal or external root resorption.

Table (2): Clinical Success and Failure.

جداول تقييم مستويات الألم

قبل العمل



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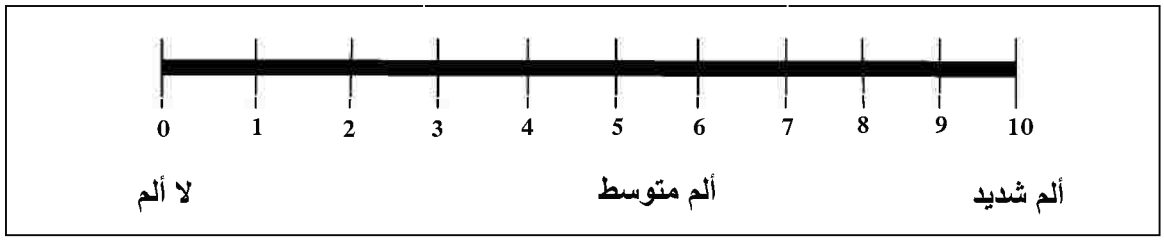

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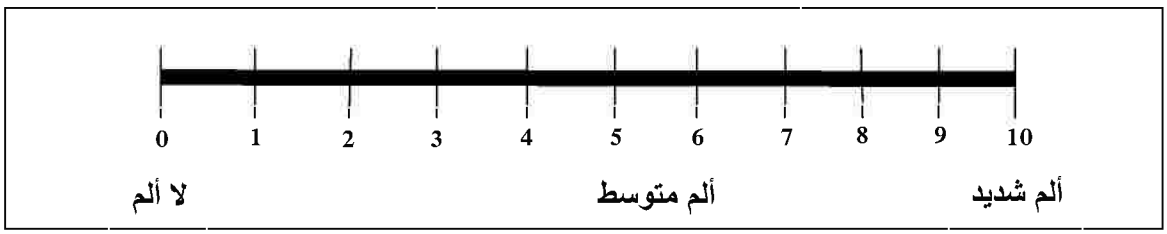
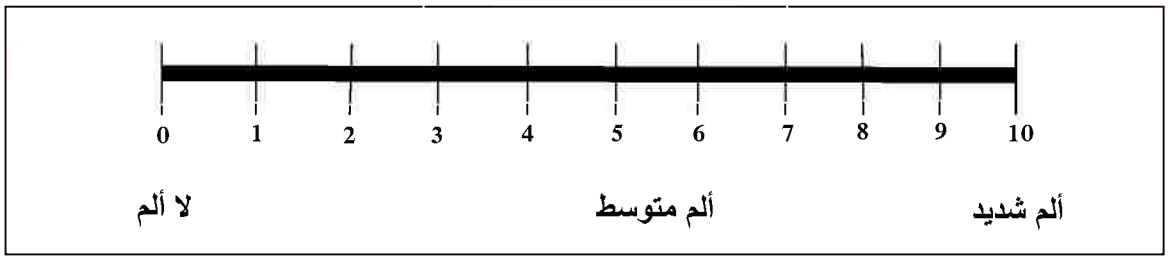


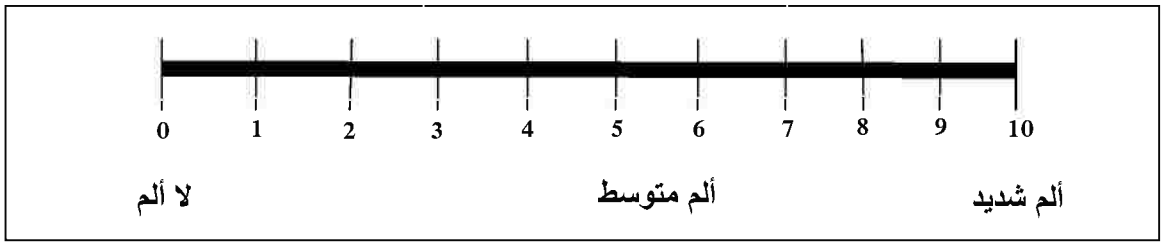
بعد (24) ساعة

Figure10A:Visual Analogue Scale (VAS)

بعد (48) ساعة



بعد (1) شهر



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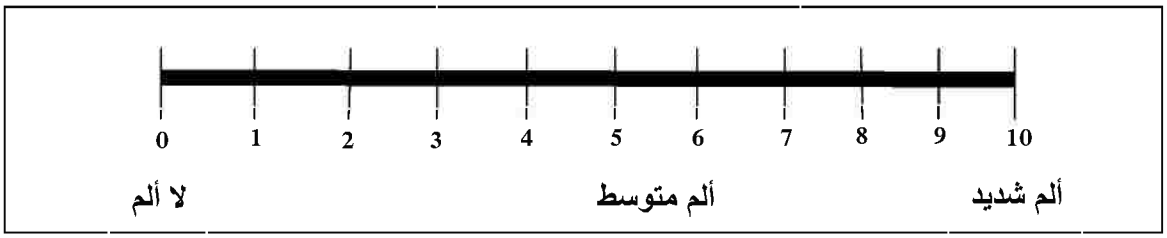

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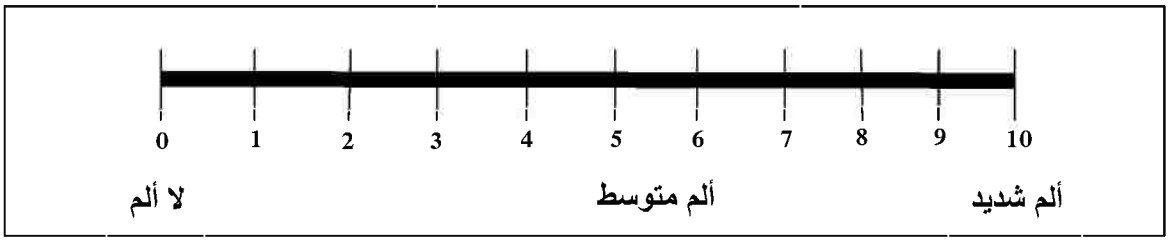


Figure 10B: Visual Analogue Scale (VAS).

1- Post- operative general instructions for the eligible participants:

The patient was informed that:

1. Each patient should fill the pain scale chart (VAS) at 8,12, 24 & 48hours after first visit accurately by marking on the line that represents the level of pain and to return it to the operator on the next visit after two days (usually we will remind him).
2. No analgesic or anti-inflammatory drugs should be used during the interval of research.
3. Participants of both groups were scheduled for follow up visits at 1, 3, 6 months post-operatively.

After all the procedures completed, we started to collect the results and then sent it to make the statistics [127].

H-Statistical analysis:

Numerical data were presented as mean and standard deviation (SD) values. Age data showed parametric distribution; so Student's t-test was used to compare between the two groups. VAS data showed non-parametric distribution; so Mann-Whitney U test [128] was used to compare between the two groups. This test is the non-parametric alternative to Student's t-test. Wilcoxon signed-rank test [129] was used to study the changes by time within each group. This test is the non-parametric alternative to paired t-test.

Qualitative data were presented as frequencies and percentages. Chi-square (x^2) [130] test was used to compare between the two groups. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

® IBM Corporation, NY, USA.

Results

I. Demographic data

There was no statistically significant difference between mean age values, gender distributions and examined teeth in the two groups.

Table (3): Mean, standard deviation (SD), frequencies (n), percentages and results of Student's t-test and Chi-square (x^2) test for comparison between demographic data in the two groups

Group / Variables	Group A (Calcium Hydroxide)	Group B (Pulpotec)	*P*-value
Age (Years)			
Mean ± SD	30.1 ± 6.7	29 ± 5.5	**0.574**
Gender (n, %)			
Male	10 (45.5)	9 (40.9)	**0.761**
Female	12 (54.5)	13 (59.1)	
Tooth (n, %)			
Mandibular	12 (54.5)	16 (72.7)	**0.210**
Maxillary	10 (45.5)	6 (27.3)	

**: Significant at $P \leq 0.05$*

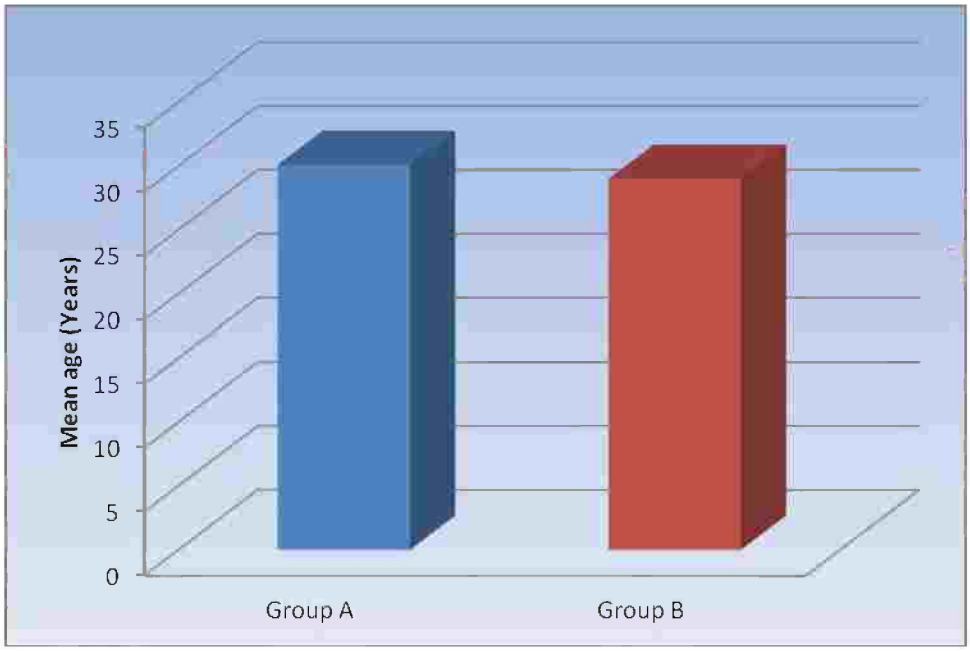


Figure (11): Bar chart representing mean age values in the two groups

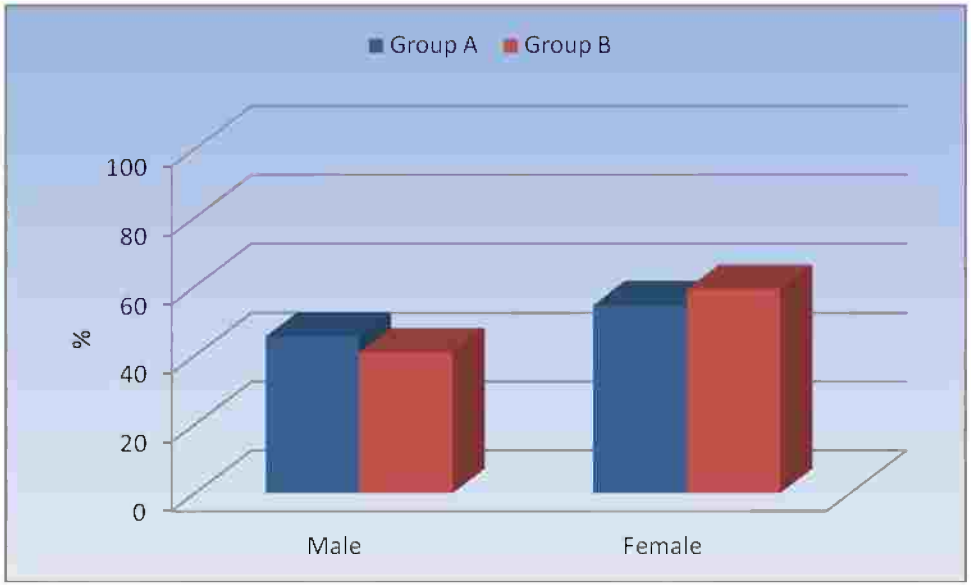


Figure (12): Bar chart representing gender distributions in the two groups

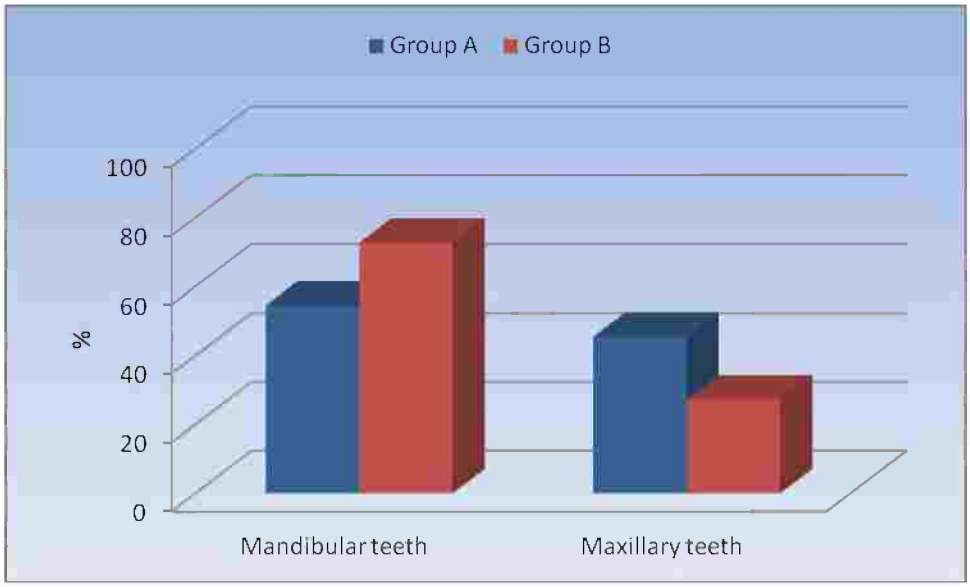


Figure (13): Bar chart representing examined teeth in the two groups

II. Clinical and radiographic follow up

After 1 month, Group A showed statistically significantly higher prevalence of pain on percussion than Group B. After 3 months and 6 months, all cases in Group A needed root canal treatment while no cases in Group B had pain noting that 2 cases didn't attend the follow up after 1 month.

After 1 month, there was no statistically significant difference between prevalence of periapical radiolucency in the two groups. After 3 months and 6 months, all cases in Group A needed root canal treatment while all cases in Group B showed no radiographic manifestations.

Table (4): Frequencies (n), percentages and results of Chi-square (x^2) test for comparison between clinical and radiographic findings in the two groups

Group / Variables	Group A (Calcium Hydroxide)	Group B (Pulpotec)	*P*-value
Pain on percussion (n, %)	22 (100)	0 (0)	**<0.001***
Periapical radiolucency (n, %)	3 (13.6)	0 (0)	**0.073**

*: *Significant at P ≤ 0.05*

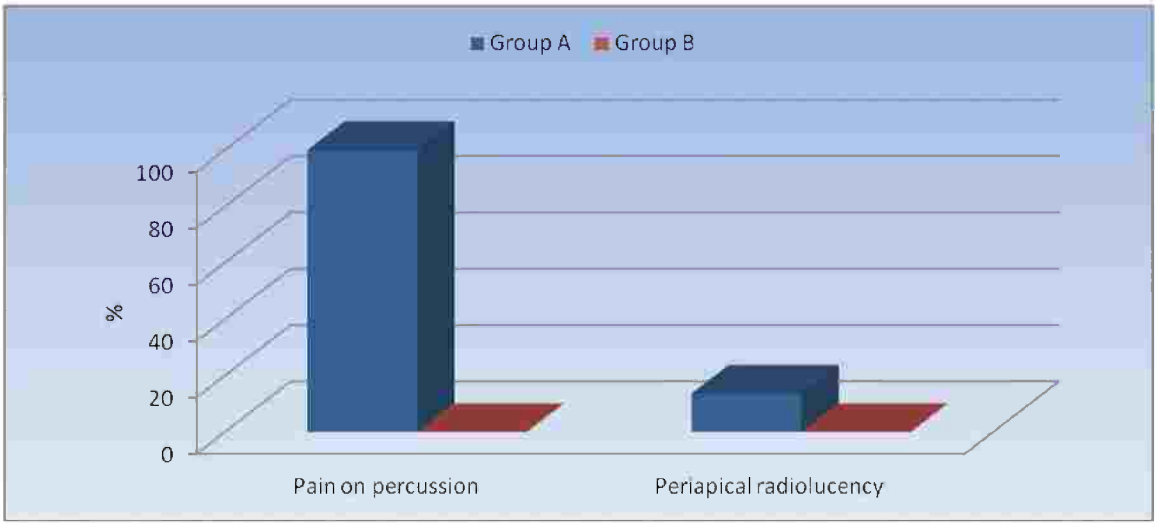


Figure (14): Bar chart representing clinical and radiographic findings in the two groups

III. Pain (VAS scores)

Comparison between mean VAS in the two groups

Pre-operatively and after 8 hours; there was no statistically significant difference between the two groups. After 12 hours and 24 hours; Group A showed statistically significantly higher mean VAS score than Group B. After 48 hours, there was no statistically significant difference between the two groups. After 1 month; Group A showed statistically significantly higher mean VAS score than Group B.

Table (5): Mean, standard deviation (SD) values and results of Mann-Whitney U test for comparison between VAS in the two groups

Group / Period	Group A (Calcium Hydroxide)		Group B (Pulpotec)		*P*-value
	Mean	SD	Mean	SD	
Pre-operative	9.6	0.5	9.4	0.7	**0.345**
After 8 hours	4	0.8	4	1.3	**0.951**
After 12hours	2	0.6	1.5	0.9	**0.031***
After 24hours	0.7	0.8	0.1	0.4	**0.003***
After 48hours	0	0	0	0	**1.000**
After 1month	8.8	1.1	0	0	**<0.001***

**: Significant at $P \leq 0.05$*

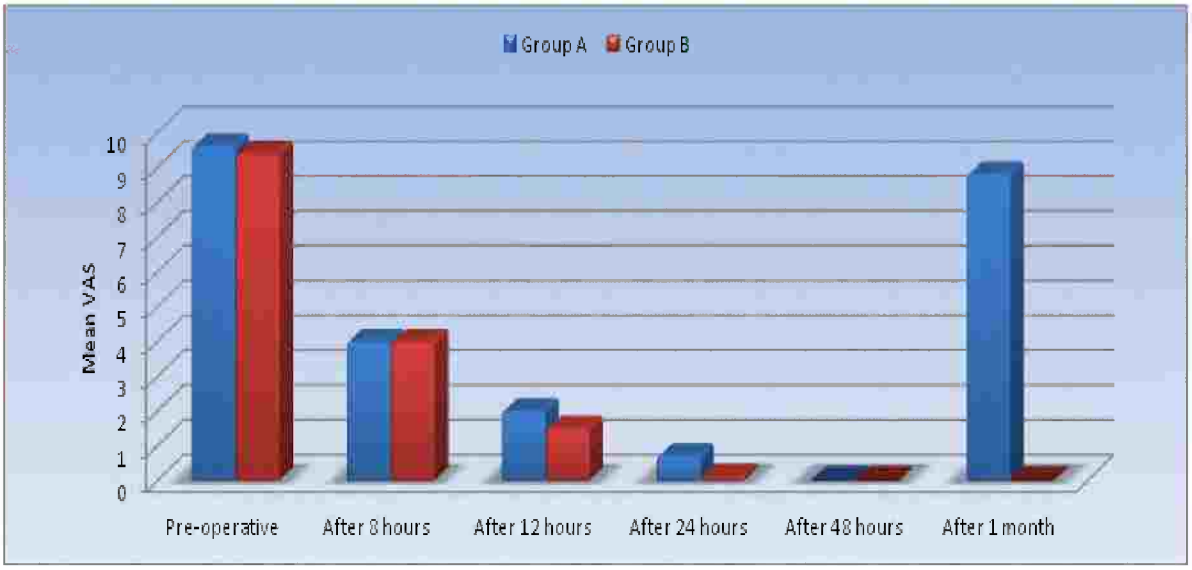


Figure (15): Bar chart representing mean VAS in the two groups

Changes by time in VAS of Group A:

There was a statistically significant decrease in mean VAS through all periods.

Table (6): Mean, standard deviation (SD) values and results of Wilcoxon signed-rank test for the changes by time within Group A

Period	Mean difference	SD	*P*-value
Pre-operative 8 hours	-5.5	0.9	**<0.001***
Pre-operative 12 hours	-7.6	0.8	**<0.001***
Pre-operative 24 hours	-8.9	0.9	**<0.001***
Pre-operative 48hours	-9.6	0.5	**<0.001***
Pre-operative 1 month	-0.8	1.1	**0.004***

**: Significant at $P \leq 0.05$*

Changes by time in VAS of Group B

There was a statistically significant decrease in mean VAS through all periods.

Table (7): Mean, standard deviation (SD) values and results of Wilcoxon signed-rank test for the changes by time within Group B

Period	Mean difference	SD	*P*-value
Pre-operative – 8 hours	-5.3	1	**<0.001***
Pre-operative – 12 hours	-7.9	0.9	**<0.001***
Pre-operative –24 hours	-9.2	0.8	**<0.001***
Pre-operative –48 hours	-9.4	0.7	**<0.001***
Pre-operative – 1 month	-9.4	0.7	**<0.001***

**: Significant at $P \leq 0.05$*

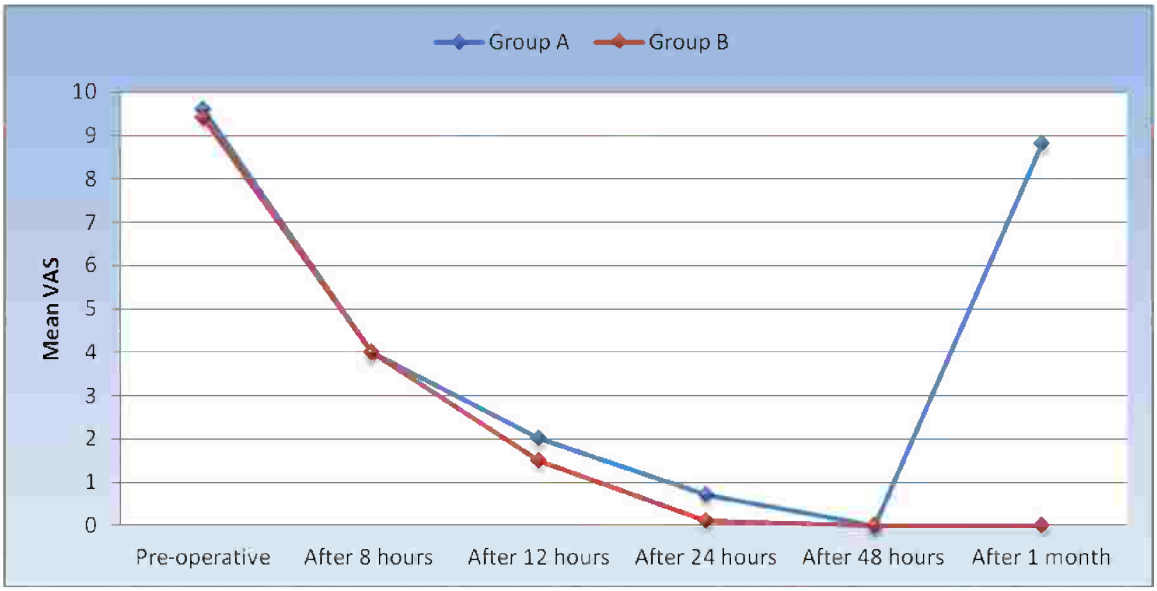


Figure (16): Line chart representing changes by time in mean VAS of the two groups

IV. Severity of pain

According to the Pre-operatively, all cases had severe pain. Although After 8 hours and 12 hours, there was no statistically significant difference between the two groups, after 24 hours, Group B showed statistically significantly higher prevalence of no pain than Group A which showed higher prevalence of mild pain. However, after 48 hours, all cases had no pain.

Regarding to 1 month post operatively, Group B showed statistically significantly higher prevalence of no pain in contrary Group A showed higher prevalence of severe pain.

Table (8): Frequencies (n), percentages **and results of Chi-square (x^2) test for comparison between severity of pain in the two groups**

Period	Group / Degree of pain (n, %)	Group A (Calcium Hydroxide)	Group B (Pulpotec)	*P*-value
Preoperative	**Severe pain**	22 (100)	22 (100)	**NC****
After 8 Hours	**No pain** **Mild pain** **Moderate pain** **Severe pain**	0 (0) 6 (27.3) 16 (72.7) 0 (0)	0 (0) 8 (36.4) 14 (63.6) 0 (0)	**0.517**
After 12 hours	**No pain** **Mild pain** **Moderate pain** **Severe pain**	0 (0) 22 (100) 0 (0) 0 (0)	2 (9.1) 20 (90.9) 0 (0) 0 (0)	**0.148**
After 24 hours	**No pain** **Mild pain**	10 (45.5) 12 (54.5)	19 (86.4) 3 (9.1)	**0.004***
After 48 hours	**No pain**	22 (100)	22 (100)	**NC****
After 1 month	**No pain** **Severe pain**	0 (0) 22 (100)	22 (100) 0 (0)	**<0.001***

: Significant at P ≤ 0.05, NC: Not computed because the variable is constant*

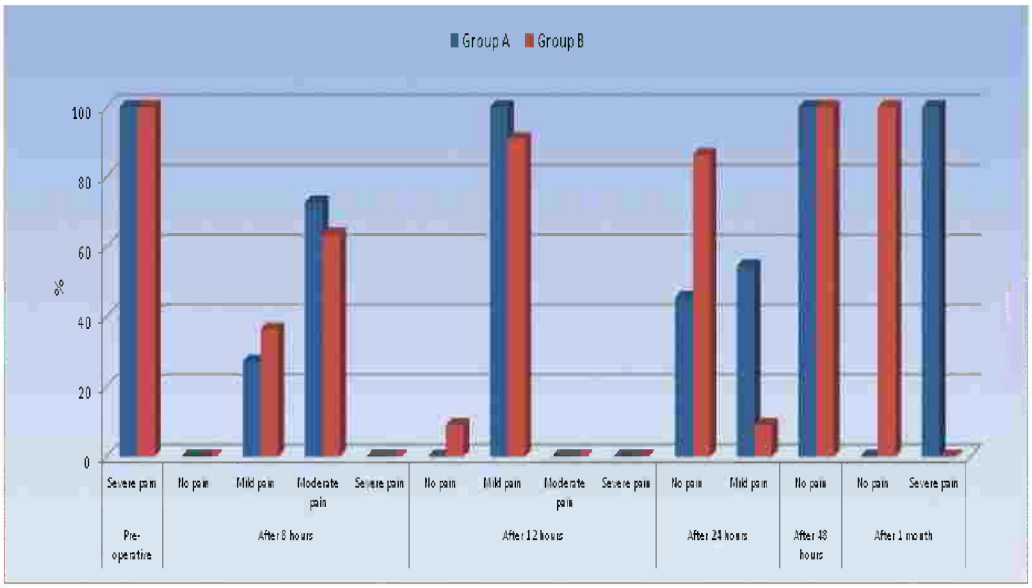


Figure (17): Bar chart representing severity of pain in the two groups

Case Report (1)

1-Personal data

Randomization No: 24

Group : A

Sex : Female

Age : 34

2- History:

- **Medical history :** Not contributory
- **Dental history and chief complaint:**

The patient was referred to the postgraduate endodontic clinic complaining about pain in the lower right first molar, which increased on biting, she had disability to withstand the cold beverages as the pain intensified to sever pain lingered for minutes.

3- Clinical and Radiographic examination:

a) Clinical findings:

- **Extraoral:** Normal

- **Intraoral:**

- **Soft tissues:** Normal
- **Offending tooth:** lower left first molar with extensive carious lesion, the tooth was tender to the percussion. By pulpation no swelling was found.
- **Other:** No signs of periodontal pathology. The other teeth in the upper and right quadrants showed no signs relevant to chief complaint.
- **Pre-operative visual analogue pain scale value:** 9 (moderate to severe pain)

b) Radiographic findings:

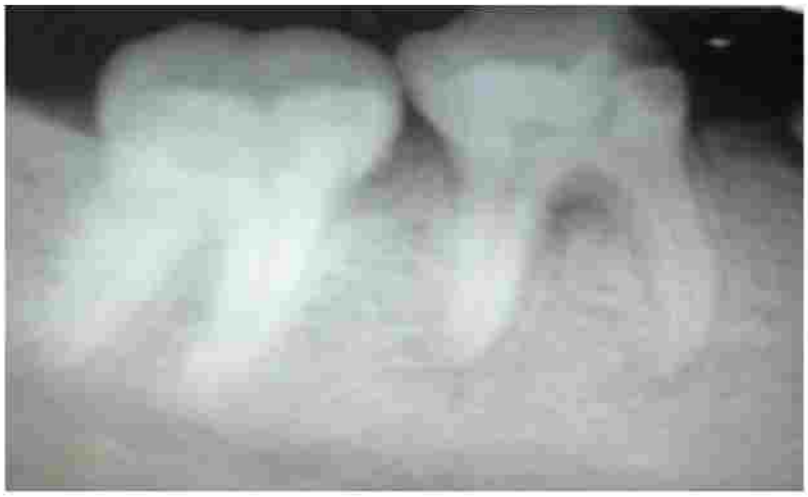


Figure (18): Preoperative X-Ray case report (1)

- **Periodontal:** the periodontal ligament space showed slightly widening following along the roots.

- **Dental:** following excavation of caries an extensive carious lesion can be demonstrated radiographically.

4-Diagnosis: Acute pulpitis with apical periodontitis.

5- **Treatment plane:**

Standard pulpotomy procedure followed by placement of Calcium hydroxide dressing in pulp chamber with overlying protecting zinc phosphate cement base and restoration of the tooth with permanent amalgam restoration.

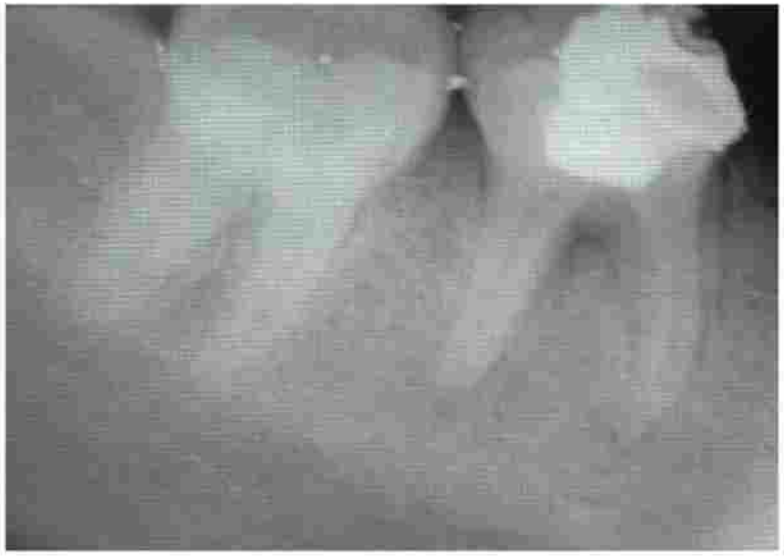


Figure (19): Postoperative X-Ray case report (1)

6- Follow up:

a) Primary outcome:

**VAS value for pain at 8, 12, 24, and 48 hours postoperatively

- 8 hrs: 5 - 12 hrs: 3
- 24 hrs: 0 - 48 hrs: 0

** Analysis of pain criteria after 48 hours (compared to post operatively):

- Spintanous pain :absent.
- Pain on percussion decreased.

b) Secondary outcome:

The follow up results were as following compared to postoperative data.

- **At 1st month postoperatively:**

Patient reported severe spontaneous pain with high sensitivity to hot and cold stimuli, tenderness during biting.Patient reported pain after 21 days with increasing in the pain intensity.

VAS value: 10 (severe pain)

Clinical examination:

Clinical examination revealed intact restoration with right proper margin, but with pain on percussion and intolerance to hot and cold stimuli.

Radiographic examination:

- Slight increasing in the periodontal ligament space

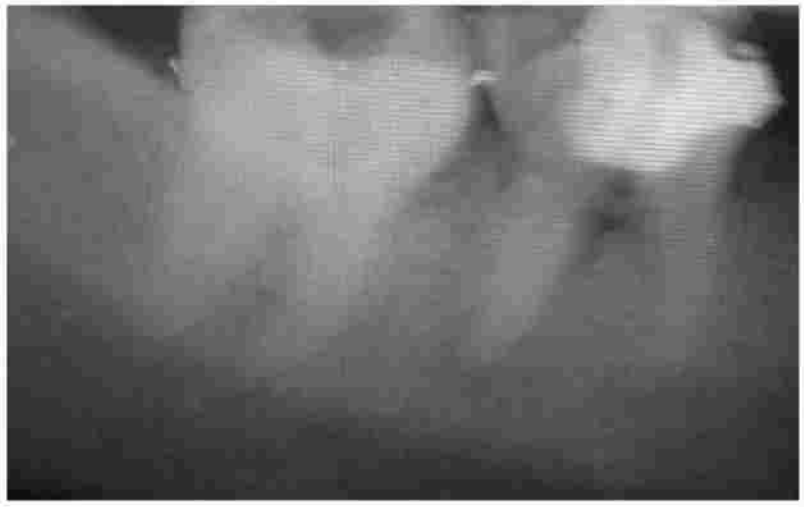


Figure (20): 1-month Postoperative X-Ray case report (1)

The case was shifted to endodontic treatment due to inability of patient to tolerate the pain as calcium hydroxide dressing failed to treat pulpitis and the periodontal inflammation.

Case Report (2)

1-Personal data

Randomization No: 32

Group : B

Sex : Male

Age : 25

2- History:

- **Medical history :** Not contributory

- **Dental history and chief complaint:**

The patient was referred to the postgraduate endodontic clinic complaining about pain in the lower left first molar, which increased on biting, he couldn't withstand the cold stimuli as the pain intensified to sever pain lingered for 10 minutes. The patient also reported to spontaneous severe pain awake him 3days before deciding to come to the clinic.

3- Clinical and Radiographic examination:

a) Clinical findings:

- **Extraoral:** Normal
- **Intraoral:**

- **Soft tissues:** Normal
- **Offending tooth:** lower left first molar with extensive carious lesion, the tooth was tender to the percussion.
- **Other:** No signs of periodontal pathology. The other teeth in the upper and right quadrants showed no signs relevant to chief complaint.
- **Pre-operative visual analogue pain scale value:** 10 (severe pain)

b) Radiographic findings:

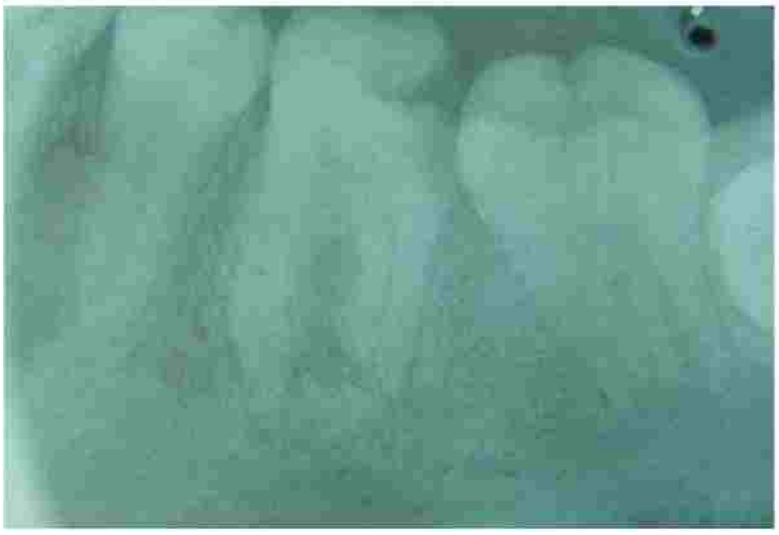


Figure (21): Preoperative X-Ray case report (2)

- **Periodontal:** the periodontal ligament space showed slightly widening following along the roots.
- **Dental:** mesio-occlusal caries can be demonstrated radiographically**.**

4-Diagnosis: Acute pulpitis with apical periodontitis.

5- Treatment plane:

Standard pulpotomy procedure followed by placement of pulpotec dressing in pulp chamber with overlying protecting zinc phosphate cement base and restoration of the tooth with permanent amalgam restoration.

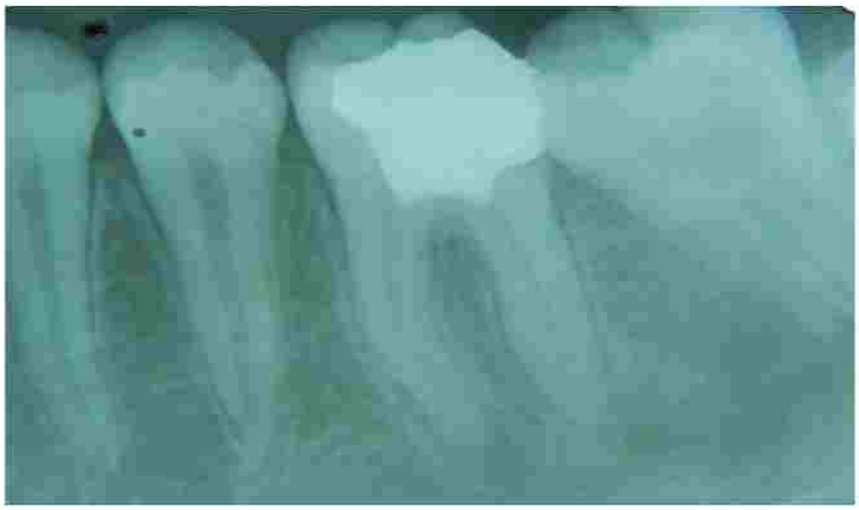


Figure (22): Postoperative X-Ray case report (2)

6- Follow up:

a) Primary outcome:

**VAS value for pain at 8, 12, 24, and 48 hours postoperatively

- 8 hrs: 5 - 12 hrs: 2
- 24 hrs: 0 - 48 hrs: 0

** Analysis of pain criteria after 48 hours (compared to post operatively):

- Spontaneous pain: absent.
- Pain on percussion decreased.

b) Secondary outcome:

The follow up results were as following compared to postoperative data.

- **At 1st month postoperatively:**

Patient reported total absent of pain even spontaneous or with cold stimuli.

VAS value: 0 (no pain).

Clinical examination:

- Intact restoration margins
- No swelling with pulpation

Radiographic examination:

- No bony changes
    - Persistant lamina dura width (not increased)
    - No radiographic evidence of recurrent caries.

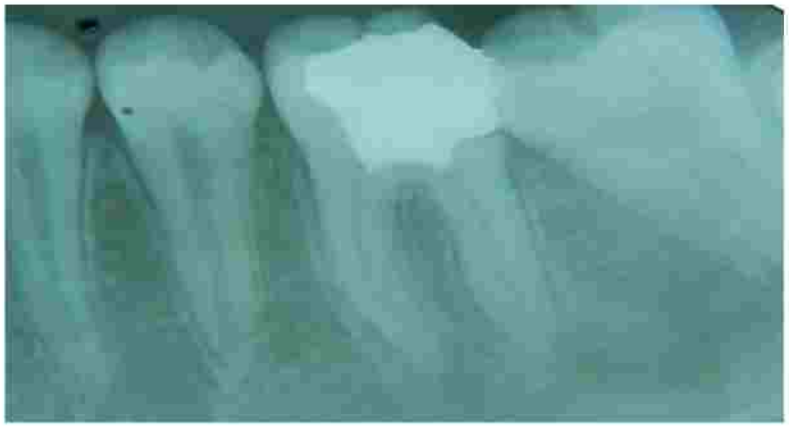


Figure (23): 1 month Postoperative X-Ray case report (2)

At 3rd month postoperatively:

Patient reported no pain attacks and he was very satisfied

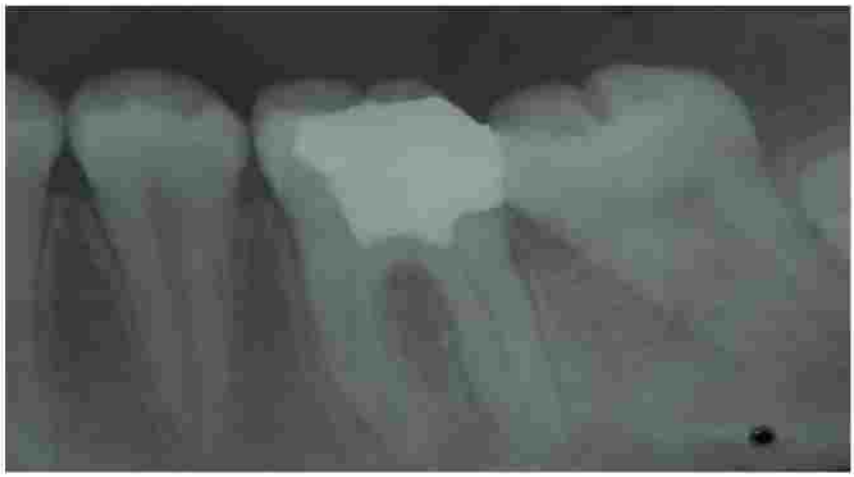
Clinical examination:

The same as the primary outcome

VAS value: 0 (no pain)

Radiographic examination:

- Normal lamina dura width
- No bony changes
- Intact radiographic restoration
- No apparent root changes



Figure(24): 3 months Postoperative X-Ray case report (2)

- **At 6 month postoperatively:**
    - Patient reported no pain attacks and no pain with biting.

Clinical examination:

No pain with percussion and the restoration margins was intact

VAS value: 0 (no pain)

Radiographic examination:

- Normal lamina dura width
- No bony changes

- Intact radiographic restoration
- No apparent root changes

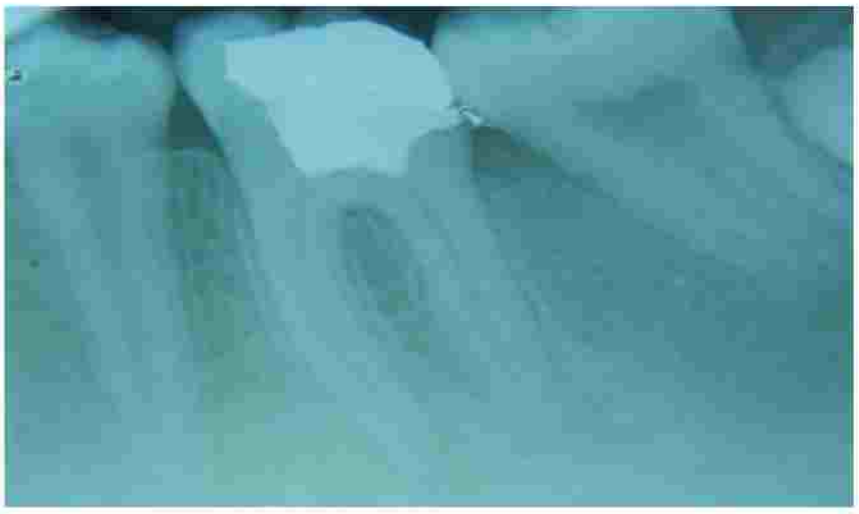


Figure (25): 6 months Postoperative X-Ray case report (2)

7- Final treatment results:

- **Primary outcome:**

Pulpotec dressing succeeded to relief the pain of acute pulpitis 48 hours postoperatively

- **Secondary outcome:**

Pulpotec dressing succeeded in maintaining pulp vitality, decreasing pulpitis and periodontitis signs and symptoms over a period of 6 months.